



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/058,350	04/10/98	SIMMS	D 0942.3840001
EXAMINER			

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ART UNIT	PAPER NUMBER

1623

DATE MAILED 03/03/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4-10-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

09/058,350  
PTOL-328 (Rev. 9/96)

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al. (Molecular Cloning: A Laboratory Manual, Second Edition; Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1989) in view of Chomczynski (5,346,994).

Claims 1 - 11 are directed to an RNA isolation reagent comprising at least one nonionic detergent (0.1 - 1.0%), a chelating agent (20 - 250 mM), a phenol (10%-60%), and a phenol stabilizer (15-55%). Claim 12 is directed to a kit containing said RNA isolation reagent.

Claims 13 - 20 are directed to the method for isolation RNA using the above reagent.

Applicant acknowledges on page 2, third full paragraph, that Sambrook et al. discloses (sections 7.6-7.9) a method for isolating RNA comprising a non-ionic detergent, phenol, RNase inhibitors, and no chaotropic agent. Sambrook et al. does not teach use of solubilizers nor the use of EDTA to inhibit RNA degradation. However, Chomczynski does teach the use of phenol (30%-50%) with a solubilizer (3% - 15%-) at claim 8. Chomczynski does not teach the use of a phenol stabilizer. However, DeBonville et al. (4,833,239) does teach the use of both a stabilizer (8-hydroxyquinoline) and a solubilizer (isopropanol) at column 4, Example 1. Finally, none of the above references teaches the use of a chelating agent in place of the more traditional RNase inhibitors. However, it is well in known in the art that

Art Unit: 1623

ribonuclease has an essential zinc ion at the catalytic site. High concentrations of a strong chelating agent will starve the enzyme for its critical zinc ion. Therefore, the claimed RNA isolation reagent, a kit containing said reagent, and a method of using the reagent to isolate RNA would have all been obvious to the person of ordinary skill in the art at the time of the invention wanting a rapid method to purify RNA without the necessity of expensive RNase inhibitors. The applicant has not shown that the concentration of the phenol solubilizer of 15% is a critical concentration versus the 10% used by Chomczynski. Thus, the claimed invention is prima facie obvious in the absence of clear and convincing evidence to the contrary. Claim 13 further comprises adding a haloalkane, such as chloroform, to the isolation reagent. This, too, is an obvious variation as shown by DeBonville at column 4, Example 1.

Claims 1 - 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant's invention is a reagent that includes more than any two of the reagents set forth in claim 1. It appears that minimally, one must have the phenol, the non-ionic detergent, and the chelating agent. If this is, in fact, the case, then the claim must be rewritten to always include these essential components.

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner

Art Unit: 1623

can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200